



Please type a plus sign (+) inside this box → [+]

PTO/SB/21 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM (to be used for all correspondence after initial filing)		Application Number	10/656,245
		Filing Date	September 8, 2003
		First Named Inventor	Gary J. MULLEN
		Group Art Unit	3762
		Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission		Attorney Docket Number	030640-2

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Notice to File Corrected Application Papers <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Declaration and Power of Attorney <input type="checkbox"/> Licensing-related Papers <input checked="" type="checkbox"/> PETITION To Make Special <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input checked="" type="checkbox"/> Copy of twelve (12) references
Remarks		<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees required or credit any overpayments to Deposit Account No. 19-2380 for the above identified docket number.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	Jerome W. Massie IV, Reg. No. 48,118 Nixon Peabody LLP 401 9 th Street, N.W. Suite 900 Washington, D.C. 20004-2128
Signature	
Date	March 29, 2004

CERTIFICATE OF MAILING		
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: 		
Type or printed name		
Signature		Date

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

FEE TRANSMITTAL FOR FY 2004

Patent fees are subject to annual review.

☐ Applicant claims small entity status. See 37 CFR 1.101.

TOTAL AMOUNT OF PAYMENT

(\$ 130)

Complete if Known

Application Number

To Be Assigned

Filing Date

September 8, 2003

First Named Inventor

Gary J. MULLEN

Examiner Name

To Be Assigned

Art Unit

3762

Attorney Docket No.

030640-2

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number

19-2380

Deposit Account Name

Nixon Peabody LLP

The Commissioner is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee (\$)	Small Entity Fee Code	Small Entity Fee (\$)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) (\$ 0)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
	-20** =	X	0
Independent Claims	-3** =	X	0
Multiple Dependent	X		0

Large Entity Fee Code	Large Entity Fee (\$)	Small Entity Fee Code	Small Entity Fee (\$)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$ 0)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee (\$)	Small Entity Fee Code	Small Entity Fee (\$)	Fee Description
1051	130	2051	65	Surcharge - late filing fee or oath
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet
1053	130	1053	130	Non-English specification
1812	2,520	1812	2,520	For filing a request for <i>ex parte</i> reexamination
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action
1251	110	2251	55	Extension for reply within first month
1252	420	2252	210	Extension for reply within second month
1253	950	2253	475	Extension for reply within third month
1254	1,480	2254	740	Extension for reply within fourth month
1255	2,010	2255	1,005	Extension for reply within fifth month
1401	330	2401	165	Notice of Appeal
1402	330	2402	165	Filing a brief in support of an appeal
1403	290	2403	145	Request for oral hearing
1451	1,510	1451	1,510	Petition to institute a public use proceeding
1452	110	2452	55	Petition to revive - unavoidable
1453	1,330	2453	665	Petition to revive - unintentional
1501	1,330	2501	665	Utility issue fee (or reissue)
1502	480	2502	240	Design issue fee
1503	640	2503	320	Plant issue fee
1460	130	1460	130	Petitions to the Commissioner
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)
1806	180	1806	180	Submission of Information Disclosure Stmt
8021	40	8021	40	Recording each patent assignment per property (times number of properties)
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))
1801	770	2801	385	Request for Continued Examination (RCE)
1802	900	1802	900	Request for expedited examination of a design application

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 130)

CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR 1.8(a)]

I hereby certify that this correspondence is being:

- ☐ deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Mail Stop _____, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450
- ☐ transmitted by facsimile on the date shown below to the United States Patent and Trademark Office at (703) _____

Date

Signature

Typed or printed name

SUBMITTED BY

Name (Print/Type)

Jerome W. Massie

Registration No. (Attorney/Agent)

48,118

Complete (if applicable)

Telephone

(202) 585-8000

Signature

Date

March 29, 2004

SEND TO: Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450



Application No. 10/656,245

Docket No. 030640-2

Page 1 of 14

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:)	
Gary J. MULLEN)	Examiner: Not yet assigned
Serial No. 10/656,245)	Group Art Unit: 3762
Filed: September 8, 2003)	Date: March 29, 2004
For: AN APPARATUS FOR TREATING)	
PNEUMOTHORAX AND/OR)	Confirmation No.: 8853
HEMOTHORAX)	

PETITION TO MAKE SPECIAL UNDER 37 C.F.R. § 1.102(d)

Commissioner Of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant hereby petitions under 37 C.F.R. § 1.102(d) to have the above-captioned application advanced for examination. The Manual of Patent Examination and Procedure, at Chapter 708.02 @VIII, provides, in part, that a new application may be granted special status provided that applicant (1) submits a petition to make special accompanied by the fee set forth in 37 C.F.R. 1.17(h), (2) presents all claims directed to a single invention, (3) submits a statement that a pre-examination search was made, listing the field of search by class and subclass, publication, Chemical Abstracts, foreign patents, etc., (4) submits one copy each of the references deemed most closely related to the subject matter encompassed by the claims if said references are not already of record, and (5) submits a detailed discussion of the references, which discussion points out, with the particularity required by 37 C.F.R. 1.111 (b) and (c), how the claimed subject matter is patentable over the references. (MPEP 708.02 § VIII)

In conformance with the above provision, Applicant herein asserts that the claims are directed to a single inventive concept, i.e., a device for treating a pneumothorax and method of using the device for treating a pneumothorax, and agrees, if more than one inventive concept is determined to be present, to make an election without traverse. Additionally, the

03/30/2004 CNGUYEN 00000136 192380 10656245

01 FC:1460 130.00 DA

Applicant asserts that a pre-examination search was completed on May 1, 2003. The search encompassed Class 604, subclasses 167.02, 167.03, 247, 257, and 264. Additionally, a computer database search was conducted on the USPTO systems EAST and WEST. Moreover, Examiner Kevin Sirmons in Class 604 (Art Unit 3763) was consulted in confirming the field of search.

The search yielded the references included in the Information Disclosure Statement filed December 10, 2003 in the above-identified application. Those references included the following:

<u>U.S. Patent Number</u>	<u>Inventor(s)</u>
2,154,968	Alkio
3,385,300	Holter
3,459,189	Alley et al.
3,613,684	Sheridan
3,703,899	Calinog
4,153,058	Nehme
4,813,941	Shea
5,078,689	Keller
5,344,410	Kolkin et al.
5,419,776	Baer
5,478,333	Asherman, Jr.
5,897,531	Amirana

In further conformance with the above provision, each of the above-identified references is discussed in detail below.

U.S. Patent No. 2,154,968 issued to Alkio, provides, in relevant part, that obstruction of the lachrymal duct is a disease which is very difficult to treat and remedy. In many cases, an operation would be necessary, but many patients object to this procedure. For this reason, I have made extensive experiments for the purpose of enlarging, without having recourse to an operation, the lachrymal duct by inserting into the same an element adapted to enlarge the same. To enable free flow of the tear secretion during the treatment, which may last for several weeks or months, the enlarging element is constructed in the form of a metal spiral.

However, the '968 patent does not disclose or suggest a device for treating pneumothorax, tension pneumothorax, and/or hemothorax, comprising a trocar obturator unit comprising a stylet with a distal end and a proximal end, wherein the proximal end of said stylet has a point for puncturing a body cavity, and wherein a stopper is coupled to said stylet distally of said point, a catheter assembly comprising (a) a tube dimensioned to receive said

stylet, said tube having, a lumen, an open-ended distal end portion and an open-ended proximal end portion and at least one fluid opening through the sidewall, and (b) a hub coupled to said open-ended distal end portion, wherein a lumen of said hub is continuous with the lumen of said tube and dimensioned to receive at least a portion of said stopper to position the stylet relative to the catheter assembly and seal the lumen of said hub, and a one-way valve, wherein one end of said one-way valve is sealed to at least a portion of said hub, said one-way valve being configured such that the lumen of the one-way valve is continuous with the lumens of said tube and said hub, as is claimed by the present application.

U.S. Patent No. 3,385,300 issued to Holter, provides, in relevant part, a cervical cannula comprising a tapered cone made of flexible material and having a pointed end and a blunt end, thread means molded onto the cone for easy insertion of the cone into a cervical canal and for retention and sealing of the cone therein, said thread means including a helical thread having teeth with front and rear faces extending along the cone, with the front faces of the teeth slanting toward the blunt end of the cone for easy insertion, and the rear faces of the teeth slanting towards the blunt end of the cone to aid in retention of the cone in the cervical canal, a tube extending from the blunt end of the cone to an open end through which may be passed fluids, and an opening in the pointed end of the cone for passing the fluid into the cervical canal. A stylus of bendable metal is provided for inserting the cannula, and a criss-cross fabric is molded onto the outside of the tube to aid in transmitting torque from the open end of the tube to the cone.

However, the '300 patent does not disclose or suggest a device for treating pneumothorax, tension pneumothorax, and/or hemothorax, comprising a trocar obturator unit comprising a stylet with a distal end and a proximal end, wherein the proximal end of said stylet has a point for puncturing a body cavity, and wherein a stopper is coupled to said stylet distally of said point, a catheter assembly comprising (a) a tube dimensioned to receive said stylet, said tube having, a lumen, an open-ended distal end portion and an open-ended proximal end portion and at least one fluid opening through the sidewall, and (b) a hub coupled to said open-ended distal end portion, wherein a lumen of said hub is continuous with the lumen of said tube and dimensioned to receive at least a portion of said stopper to position the stylet relative to the catheter assembly and seal the lumen of said hub, and a one-way valve, wherein one end of said one-way valve is sealed to at least a portion of said hub,

said one-way valve being configured such that the lumen of the one-way valve is continuous with the lumens of said tube and said hub, as is claimed by the present application.

U.S. Patent No. 3,459,189 issued to Alley et al., provides, in relevant part, a trocar catheter which is sterile packaged and ready for immediate use. The trocar catheter has a trocar with an abutment near its distal end which is adapted to engage an abutment extending from the internal surface of the catheter near its distal end such that the abutment on the trocar assists in placing the catheter. The trocar is suitably marked in such a way that the exact location of the catheter can be determined by reference to the trocar. The trocar and catheter have aligned end surfaces which cooperate to provide a smooth point for penetrating the area being punctured. The proximal end of the trocar is ball shaped for providing a surface which better cooperates with the physician's hand in placing the trocar. The ball shaped end of the trocar cooperates with the package for ease in storing and removing the trocar from the package. The catheter has an X-ray opaque line and drainage openings near the distal end at least one of which openings coacts with the X-ray opaque line to indicate the location of the end of the catheter in the patient under appropriate techniques. However, the '189 patent does not disclose or suggest a device for treating pneumothorax, tension pneumothorax, and/or hemothorax, comprising a trocar obturator unit comprising a stylet with a distal end and a proximal end, wherein the proximal end of said stylet has a point for puncturing a body cavity, and wherein a stopper is coupled to said stylet distally of said point, a catheter assembly comprising (a) a tube dimensioned to receive said stylet, said tube having, a lumen, an open-ended distal end portion and an open-ended proximal end portion and at least one fluid opening through the sidewall, and (b) a hub coupled to said open-ended distal end portion, wherein a lumen of said hub is continuous with the lumen of said tube and dimensioned to receive at least a portion of said stopper to position the stylet relative to the catheter assembly and seal the lumen of said hub, and a one-way valve, wherein one end of said one-way valve is sealed to at least a portion of said hub, said one-way valve being configured such that the lumen of the one-way valve is continuous with the lumens of said tube and said hub, as is claimed by the present application.

U.S. Patent No. 3,613,684 issued to Sheridan, provides, in relevant part, a trocar catheter formed with a rigid shaftlike stylet and an encircling catheter made of plastic material. The catheter has a molded rigid distal end member with a conical shape, a closed rounded tip fixed to a flexible tube, and at least one fluid opening through the side. The rigid

distal end member has an interior that conforms to the shape of the stylet tip. The device may be used in emergency cases where the catheter is forced through the chest wall of a patient over the stylet which is then withdrawn to let fluid pass through the catheter or for suprapubic cystostomy procedures.

However, the '684 patent does not disclose or suggest a device for treating pneumothorax, tension pneumothorax, and/or hemothorax, comprising a trocar obturator unit comprising a stylet with a distal end and a proximal end, wherein the proximal end of said stylet has a point for puncturing a body cavity, and wherein a stopper is coupled to said stylet distally of said point, a catheter assembly comprising (a) a tube dimensioned to receive said stylet, said tube having, a lumen, an open-ended distal end portion and an open-ended proximal end portion and at least one fluid opening through the sidewall, and (b) a hub coupled to said open-ended distal end portion, wherein a lumen of said hub is continuous with the lumen of said tube and dimensioned to receive at least a portion of said stopper to position the stylet relative to the catheter assembly and seal the lumen of said hub, and a one-way valve, wherein one end of said one-way valve is sealed to at least a portion of said hub, said one-way valve being configured such that the lumen of the one-way valve is continuous with the lumens of said tube and said hub, as is claimed by the present application.

U.S. Patent No. 3,703,899 issued to Calinog, provides, in relevant part, a trocar slidably mounted in a main tube and normally disposed at its front end. Connected to the rear end of the trocar is a rod that extends back through the tube and out its rear end. A tubular bellows encircles the rod and has a front end sealed to the trocar, while the rear end of the bellows is sealingly connected to the rear end of the tube. After the tube is inserted in an incision, the trocar is pulled back into a position near the rear end of the tube. Directly in front of this rear portion the tube is provided with a lateral outlet opening and a discharge tube so that drainage can occur back through the two tubes.

However, the '899 patent does not disclose or suggest a device for treating pneumothorax, tension pneumothorax, and/or hemothorax, comprising a trocar obturator unit comprising a stylet with a distal end and a proximal end, wherein the proximal end of said stylet has a point for puncturing a body cavity, and wherein a stopper is coupled to said stylet distally of said point, a catheter assembly comprising (a) a tube dimensioned to receive said stylet, said tube having, a lumen, an open-ended distal end portion and an open-ended proximal end portion and at least one fluid opening through the sidewall, and (b) a hub

coupled to said open-ended distal end portion, wherein a lumen of said hub is continuous with the lumen of said tube and dimensioned to receive at least a portion of said stopper to position the stylet relative to the catheter assembly and seal the lumen of said hub, and a one-way valve, wherein one end of said one-way valve is sealed to at least a portion of said hub, said one-way valve being configured such that the lumen of the one-way valve is continuous with the lumens of said tube and said hub, as is claimed by the present application.

U.S. Patent No. 4,153,058 issued to Nehme, provides, in relevant part, a pleural decompression catheter for releasing entrapped air within a human body. The device comprises an elongated member axially insertable into a human body and having fluid passage means for establishing fluid communication from the exterior of the elongated member to one end of the member positioned exteriorly of the body. A one-way valve is coupled to the exteriorly extending end of the elongated member so that entrapped air within the body can flow through the passage means in the elongated member, through the one-way valve and exhaust exteriorly of the human body.

However, the '058 patent does not disclose or suggest a device for treating pneumothorax, tension pneumothorax, and/or hemothorax, comprising a trocar obturator unit comprising a stylet with a distal end and a proximal end, wherein the proximal end of said stylet has a point for puncturing a body cavity, and wherein a stopper is coupled to said stylet distally of said point, a catheter assembly comprising (a) a tube dimensioned to receive said stylet, said tube having, a lumen, an open-ended distal end portion and an open-ended proximal end portion and at least one fluid opening through the sidewall, and (b) a hub coupled to said open-ended distal end portion, wherein a lumen of said hub is continuous with the lumen of said tube and dimensioned to receive at least a portion of said stopper to position the stylet relative to the catheter assembly and seal the lumen of said hub, and a one-way valve, wherein one end of said one-way valve is sealed to at least a portion of said hub, said one-way valve being configured such that the lumen of the one-way valve is continuous with the lumens of said tube and said hub, as is claimed by the present application.

U.S. Patent No. 4,813,941 issued to Shea, provides, in relevant part, an apparatus for providing immediate temporary treatment of pneumothorax in a patient by exhausting the pleural cavity. The apparatus incorporates an exhaustion device having a standard luer lock lug receptacle enabling use of a multiple of different size and models of pleural cavity entrance devices having standard luer lock connecting lugs. The exhaustion device also

incorporates a one-way valve on the luer lock lug receptacle for exhausting fluid from the pleural cavity and preventing fluid from flowing into the pleural cavity. Projecting wings ease the handling of the apparatus and provide tape attachment surfaces for securing of the apparatus to a patient.

However, the '941 patent does not disclose or suggest a device for treating pneumothorax, tension pneumothorax, and/or hemothorax, comprising a trocar obturator unit comprising a stylet with a distal end and a proximal end, wherein the proximal end of said stylet has a point for puncturing a body cavity, and wherein a stopper is coupled to said stylet distally of said point, a catheter assembly comprising (a) a tube dimensioned to receive said stylet, said tube having, a lumen, an open-ended distal end portion and an open-ended proximal end portion and at least one fluid opening through the sidewall, and (b) a hub coupled to said open-ended distal end portion, wherein a lumen of said hub is continuous with the lumen of said tube and dimensioned to receive at least a portion of said stopper to position the stylet relative to the catheter assembly and seal the lumen of said hub, and a one-way valve, wherein one end of said one-way valve is sealed to at least a portion of said hub, said one-way valve being configured such that the lumen of the one-way valve is continuous with the lumens of said tube and said hub, as is claimed by the present application.

U.S. Patent No. 5,078,689 issued to Keller, provides, in relevant part, a medical device useful for removing fluids from body cavities. A flexible catheter is attached to a stabilizing base with a collar forming a vestibule on the opposite side of the base. The vestibule is sealed with a stopper or diaphragm. A needle is inserted through the stopper, into the diaphragm, through a central hole in the base and through the lumen of the catheter and out the terminal hole of the catheter. After insertion into the body, the needle is withdrawn leaving the catheter and base in place for drainage. The unit is a self sealing structure to prevent introduction of contamination of ambient air.

However, the '689 patent does not disclose or suggest a device for treating pneumothorax, tension pneumothorax, and/or hemothorax, comprising a trocar obturator unit comprising a stylet with a distal end and a proximal end, wherein the proximal end of said stylet has a point for puncturing a body cavity, and wherein a stopper is coupled to said stylet distally of said point, a catheter assembly comprising (a) a tube dimensioned to receive said stylet, said tube having, a lumen, an open-ended distal end portion and an open-ended proximal end portion and at least one fluid opening through the sidewall, and (b) a hub

coupled to said open-ended distal end portion, wherein a lumen of said hub is continuous with the lumen of said tube and dimensioned to receive at least a portion of said stopper to position the stylet relative to the catheter assembly and seal the lumen of said hub, and a one-way valve, wherein one end of said one-way valve is sealed to at least a portion of said hub, said one-way valve being configured such that the lumen of the one-way valve is continuous with the lumens of said tube and said hub, as is claimed by the present application.

U.S. Patent No. 5,344,410 issued to Kolkin et al., provides, in relevant part, a device comprising an outer tube having a central canal and perforations at its one end, a stylet fitted in the central canal of the outer tube, an inner tube, which is in fact a non-return valve and with its one end tightly connected to the outer tube and with its opposite end stretched over the stylet with a possibility of slipping off the latter and getting everted. The device has a receptacle for collecting the pleural fluid, tightly connected to the outer tube and the inner tube, and a retainer for fixing the device in position.

However, the '410 patent does not disclose or suggest a device for treating pneumothorax, tension pneumothorax, and/or hemothorax, comprising a trocar obturator unit comprising a stylet with a distal end and a proximal end, wherein the proximal end of said stylet has a point for puncturing a body cavity, and wherein a stopper is coupled to said stylet distally of said point, a catheter assembly comprising (a) a tube dimensioned to receive said stylet, said tube having, a lumen, an open-ended distal end portion and an open-ended proximal end portion and at least one fluid opening through the sidewall, and (b) a hub coupled to said open-ended distal end portion, wherein a lumen of said hub is continuous with the lumen of said tube and dimensioned to receive at least a portion of said stopper to position the stylet relative to the catheter assembly and seal the lumen of said hub, and a one-way valve, wherein one end of said one-way valve is sealed to at least a portion of said hub, said one-way valve being configured such that the lumen of the one-way valve is continuous with the lumens of said tube and said hub, as is claimed by the present application.

U.S. Patent No. 5,419,776 issued to Baer, provides, in relevant part, an apparatus for treating pneumothorax and pneumohemothorax comprising a one-way valve having a top end and a bottom end and a suction port secured to and extending beyond the top end, a conduit secured to and extending perpendicularly away from the bottom end of the one-way valve in flow communication therewith a 90 degree elbow removably securable to a distal end of the conduit in flow communication therewith and a luer lock lug receptacle secured to the 90

degree elbow and adapted to threadingly receive luer lock lugs on a large bore needle or catheter. The 90 degree elbow is removably securable to the conduit and may be removed and replaced with a connection adapter. The connection adaptor has a first end removably securable to the distal end of the conduit and a second end removably securable to a chest tube surgically inserted in the pleural space. The apparatus may also include an injection port extending from and in flow communication with the conduit. The injection port being adapted to receive a needle such that an aqueous solution may be directed toward said one-way valve from said needle.

However, the '776 patent does not disclose or suggest a device for treating pneumothorax, tension pneumothorax, and/or hemothorax, comprising a trocar obturator unit comprising a stylet with a distal end and a proximal end, wherein the proximal end of said stylet has a point for puncturing a body cavity, and wherein a stopper is coupled to said stylet distally of said point, a catheter assembly comprising (a) a tube dimensioned to receive said stylet, said tube having, a lumen, an open-ended distal end portion and an open-ended proximal end portion and at least one fluid opening through the sidewall, and (b) a hub coupled to said open-ended distal end portion, wherein a lumen of said hub is continuous with the lumen of said tube and dimensioned to receive at least a portion of said stopper to position the stylet relative to the catheter assembly and seal the lumen of said hub, and a one-way valve, wherein one end of said one-way valve is sealed to at least a portion of said hub, said one-way valve being configured such that the lumen of the one-way valve is continuous with the lumens of said tube and said hub, as is claimed by the present application.

U.S. Patent No. 5,478,333 issued to Asherman, Jr., provides, in relevant part, a medical dressing for treating open chest injuries, or other injuries that compromise or could possibly compromise the pleural space of the chest cavity. Specifically, a medical dressing used by first responders to treat an open pneumothorax, treat and/or prevent a tension pneumothorax from developing, remove the accumulated blood of a hemothorax or re-inflating a collapsed lung without invasive procedures and in some instances act as a conduit for treating a tension pneumothorax or a collapsed lung with invasive procedures.

However, the '333 patent does not disclose or suggest a device for treating pneumothorax, tension pneumothorax, and/or hemothorax, comprising a trocar obturator unit comprising a stylet with a distal end and a proximal end, wherein the proximal end of said stylet has a point for puncturing a body cavity, and wherein a stopper is coupled to said stylet

distally of said point, a catheter assembly comprising (a) a tube dimensioned to receive said stylet, said tube having, a lumen, an open-ended distal end portion and an open-ended proximal end portion and at least one fluid opening through the sidewall, and (b) a hub coupled to said open-ended distal end portion, wherein a lumen of said hub is continuous with the lumen of said tube and dimensioned to receive at least a portion of said stopper to position the stylet relative to the catheter assembly and seal the lumen of said hub, and a one-way valve, wherein one end of said one-way valve is sealed to at least a portion of said hub, said one-way valve being configured such that the lumen of the one-way valve is continuous with the lumens of said tube and said hub, as is claimed by the present application.

U.S. Patent No. 5,897,531 issued to Amirana, provides, in relevant part, a surgical retainer device for temporarily, but movably, affixing in place, a tube or catheter as it passes through the skin or enters a body cavity. The retainer is adhesively attached to the skin and is constructed in such a way to hold firmly the tube or catheter that penetrates the skin and enters a space within the body. The device may be used to place a medication or ointment at the site of the skin entry. The retainer utilizes a compression or friction fitting which allows the tube or catheter to be moved in or out of the opening through the skin. The device is especially suitable for retaining a chest tube during treatment of pneumothorax although its use is not so limited. However, the '531 patent does not disclose or suggest a device for treating pneumothorax, tension pneumothorax, and/or hemothorax, comprising a trocar obturator unit comprising a stylet with a distal end and a proximal end, wherein the proximal end of said stylet has a point for puncturing a body cavity, and wherein a stopper is coupled to said stylet distally of said point, a catheter assembly comprising (a) a tube dimensioned to receive said stylet, said tube having, a lumen, an open-ended distal end portion and an open-ended proximal end portion and at least one fluid opening through the sidewall, and (b) a hub coupled to said open-ended distal end portion, wherein a lumen of said hub is continuous with the lumen of said tube and dimensioned to receive at least a portion of said stopper to position the stylet relative to the catheter assembly and seal the lumen of said hub, and a one-way valve, wherein one end of said one-way valve is sealed to at least a portion of said hub, said one-way valve being configured such that the lumen of the one-way valve is continuous with the lumens of said tube and said hub, as is claimed by the present application.

Finally, enclosed is a copy of the claims of the above-identified patent application as originally filed. None of the references satisfies the need in the art for a device that can be

safely used by less experienced medical personnel, including first responders, to quickly and easily treat patients suffering from pneumothorax, tension pneumothorax, and/or hemothorax on battlefields, conditions of mass casualty, conditions of environmental chemical, biologic, or radiologic contamination, as well as in more conventional settings, such as within ambulances and hospitals, as is provided by the claims of the present application.

Submitted herewith is the fee required under 37 C.F.R. 1.17(h). In view thereof, it is respectfully requested that this application be accorded "special" status under 37 C.F.R. 102(d).

If additional information is required, please contact the undersigned.

Respectfully submitted,
NIXON PEABODY LLP

By: 

Jerome W. Massie IV
Registration No. 48,118

NIXON PEABODY LLP
Suite 900
401 9th Street, N.W.
Washington, DC 20004-2128

Telephone: (202) 585-8000
Facsimile: (202) 585-8080

JWM/SMH

1. A device for treating pneumothorax, tension pneumothorax, and/or hemothorax, comprising:

a trocar obturator unit comprising a stylet with a distal end and a proximal end, wherein the proximal end of said stylet has a point for puncturing a body cavity, and wherein a stopper is coupled to said stylet distally of said point;

a catheter assembly comprising (a) a tube dimensioned to receive said stylet, said tube having, a lumen, an open-ended distal end portion and an open-ended proximal end portion and at least one fluid opening through the sidewall, and (b) a hub coupled to said open-ended distal end portion, wherein a lumen of said hub is continuous with the lumen of said tube and dimensioned to receive at least a portion of said stopper to position the stylet relative to the catheter assembly and seal the lumen of said hub; and

a one-way valve, wherein one end of said one-way valve is sealed to at least a portion of said hub, said one-way valve being configured such that the lumen of the one-way valve is continuous with the lumens of said tube and said hub.

2. The device claim 1, wherein the point on the proximal end of said stylet extends beyond the proximal end portion of said tube when said stylet is inserted into said catheter assembly.

3. The device of claim 1, wherein the diameter of said stopper is larger than the diameter of the lumen of said one-way valve.

4. The device of claim 1, wherein at least a portion of said stopper is removably retainable in at least a portion of said hub.

5. The device of claim 1, wherein at least one of the exterior of said stopper or the interior of said one-way valve is coated with a lubricant.

6. The device of claim 1, wherein said trocar obturator unit further comprises a pull-handle attached to said stopper.

7. The device of claim 1, wherein said pull-handle is a ring.
8. The device of claim 1, wherein said pull-handle is a tab.
9. The device of claim 1, wherein an annular recess is formed in the outside wall of said hub.
10. The device of claim 9, wherein said one-way valve is secured to said hub by a retaining ring positioned over said one-way valve within said recess.
11. The device of claim 9, wherein said one-way valve is secured to said hub by at least one band unwindably positioned over said one-way valve within the recess of said hub, and wherein an at least one adhesively-coated tab is attached to said at least one band for securing said device to a patient.
12. The device of claim 11, wherein said at least one tab includes a removable covering for maintaining said adhesive during periods of non-use.
13. The device of claim 1, further comprising a disk coupled to said catheter assembly for securing said trocar unit to a patient.
14. The device of claim 6, wherein at least one of said stylet, catheter assembly, one-way valve, and pull-handle, are composed of a radio-opaque material.
15. The device of claim 1, wherein said tube is kink-resistant.
16. The device of claim 1, wherein said tube is composed of coiled monofilament polymer fiber coated with a biologically inert plastic.
17. A method of treating a pneumothorax, tension pneumothorax, and/or hemothorax comprising the steps of (a) inserting at least the proximal portion of the device of claim 1 into

the affected site within the body cavity of a patient, and (b) removing the trocar obturator unit from the catheter assembly.